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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------|-------------|----------------------|---------------------|-------------------|
| 10/022,607 | 12/17/2001 | Ni Ding | 10177-103 | 5308 |
| 20583 | 7590 | 02/11/2003 | | |
| PENNIE AND EDMONDS 1155 AVENUE OF THE AMERICAS NEW YORK, NY 100362711 | | | EXAMINER | GILPIN, CRYSTAL M |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 10/022,607 | DING ET AL. |
| Examiner | Art Unit | |
| Crystal M Gilpin | 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-29 is/are rejected.

7) Claim(s) 13 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claim 13 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. Claims 1, 3, 8, 10, 11, 12, 19, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolff et al. (USPN 5,545,208).

Regarding claim 1, 3, 8, 12 and 19, Wolff et al. discloses an expandable (by balloon or self-expanding, Column 10) metal stent with openings (Figure 1) with a coating of hydrophobic biostable elastomeric material and a biologically active material or drug (Column 6, lines 60-63) that conforms to the structure and preserves the openings of the stent (Figures 12 and 13). The openings are substantially free of webbing (Figure 1) and the drug can be incorporated in the outer layer and can be made of silicone (Column 9, Lines 23-35).

Regarding claim 10, 11, 21 and 22, Wolff et al. disclose that the biological elastomeric material could be a silicone, polyurethane or other polymer (Column 7, Lines 50-67 and Column 9, Lines 33-34), where it is inherent to use a silicone, which is polysiloxane, Wolff et al. further disclose that the biologically active material is selected from heparin (Column 5, lines 40-42) and dexamethasone (Column 6, Lines 11-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2, 4, 5, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (USPN 5,545,208) in view of Lambert (USPN 5,900,246).

Regarding claim 2, Wolff et al. discloses of a coated stent but lacks the teaching of the thickness and composition of the coating. Lambert teaches of a stent with a polyurethane coating that has a thickness between 25 and 500 microns to vary the degree of swelling of the coating for drug release (Column 4, lines 27-30), overlapping the ranges disclosed by the applicant. Lambert further teaches that the composition of the polymer coating can have a 1:20 or 5% ratio of solvent to non-solvent to achieve the desired rate of evaporation (Column 4, lines 36-52), falling within the 4 to 6% range disclosed by the applicant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wolff et al. to specify the thickness and composition of the coating in order to account for swelling and solubility of the compounds within the coating.

3. Claims 6, 7, 9, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (USPN 5,545,208) in view of Berg et al. (USPN 5,464,650).

Regarding claims 6, 7, 9, 17, 18 and 20 Wolff et al. disclose a coated stent, however they lack the teaching of how the stent is coated. Berg et al. teach of a stent made of tantalum or stainless steel (Column 3, Lines 35-40) that is coated by a spraying method while being rotated (Column 5, Example 1). Berg et al. further teach that the stent is coated while in the expanded position (Column 6, Example 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wolff et al. to have the metallic stent made of stainless steel, titanium or another metal for strengthened physical properties, and to coat the stent while rotating it in an expanded state to ensure a coating of even thickness.

4. Claims 23 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert (USPN 5,900,246).

Regarding claim 23, Lambert teaches of a stent with a coating of 25 to 500 microns in thickness, comprising a biostable elastomeric material such as polyurethane and a biologically active material such as dexamethasone (Column 3). Lambert lacks the teaching of conforming the coating to preserve the openings of the stent, however it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the coating to only the struts of the stent thus preserving the openings to allow for tissue ingrowth.

Regarding claims 26-28, Lambert teaches of a coated stent, however Lambert lacks the teaching of the process by which the stent is coated. However, the final product, a coated stent, is taught in the prior art and therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed coating process to apply a coating to the stent for anti-inflammatory purposes (see MPEP 2113).

5. Claims 24, 25 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert (USPN 5,900,246) in view of Wolff et al. (USPN 5,545,208).

Regarding claims 24, 25 and 29, Lambert teaches of a coating stent but lacks the teaching of preserving web-free stent openings or multiple coating layers. Wolff et al. teach of a stent that is coated in a manner that preserves the stent openings, and that the openings are web-free (Figure 1). Wolff et al. further teach that there can be several polymer coating layers on the stent (Column 9, Lines 23-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lambert to apply the coating or

multiple coatings to the struts of the stent thus preserving the openings and allowing for tissue ingrowth.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Tuch (USPN 5,624,411): Note the air pressure for applying solvent to the stent in

Example 9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg
February 6, 2003


Paul B. Prebilic
Primary Examiner